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Attachment D: 510(k) Summary K061538

JUN 30 2006

CRystalView® R200 Computed Radiography System

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter: Alara, Inc.
47505 Seabridge Drive
Fremont, CA 94538

Contact Person: Diane King
VP Regulatory Affairs
Phone: 510-315-5173
Fax: 510-315-5201

Date Prepared: May 30, 2006

Trade Name: CRystalView® R200 Computed Radiography System

Common Name: Computed Radiography (CR) System

Classification Name: Solid State X-Ray Imager (per 21 CFR 892.1650)

Predicate Devices:		510(k)#
	Alara CRystalView CR System	K032210
	Agfa ADC Compact	K974597

Product Description:
The Alara CRystalView® R200 is a desktop Computed Radiography (CR) system designed to generate digital x-ray images by reading photostimulable phosphor image plates exposed using standard X-ray systems and techniques. The system consists of a CR Reader, a QC Workstation with software, cassettes, and image plates. Image data is sent via a dedicated connection from the Reader to the CRystalView R200 QC Workstation, where it is processed and displayed for review. The system outputs images and patient information to a PACS using the standard DICOM 3.0 protocol. The fully configured CRystalView R200 System includes acquisition console software and post-processing image enhancement software. A reseller may alternatively provide these two software components or appropriately cleared equivalents, as well as the QC Workstation hardware.

Indications for Use:
CRystalView R200 is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures.

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Rationale for Substantial Equivalence:
CRystalView R200 has the same indication for use as the predicate devices. CRystalView R200 shares the same technological characteristics as the predicate devices. However, the descriptive characteristics are not sufficiently precise to assure substantial equivalence. Therefore, Alara has carried out verification and image quality performance testing, including a confirmatory clinical concurrence study. The results of this testing demonstrate that CRystalView R200 is substantially equivalent to the predicate devices.

Safety and Effectiveness Information:
CRystalView R200 is a Class II medical device and a Class I laser product. CRystalView R200 complies with applicable FDA and international standards pertaining to electrical, mechanical, EMC, and laser safety of medical and/or laser devices.

Alara has performed laboratory and clinical studies to demonstrate that CRystalView R200 performance characteristics and diagnostic capabilities are equivalent to the predicates. The results of these studies show that CRystalView R200 performance characteristics are comparable with those of the predicate devices. Clinically, no statistically significant difference was found in image quality ratings of CRystalView R200 and the Agfa ADC Compact when images were judged by a radiologist.

Conclusion:
CRystalView R200 performance tests and clinical studies have demonstrated that CRystalView R200 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Diane M. King
Vice President, Regulatory Affairs
Alara, Inc.
47505 Seabridge Drive
FREMONT CA 94538

AUG 23 2013

Re: K061538
Trade/Device Name: Alara CRystalView® R200 Computed Radiography System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: June 1, 2006
Received: June 2, 2006

Dear Ms. King:

This letter corrects our substantially equivalent letter of June 30, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Attachment B: Indications for Use Statement

510(k) Number: K061538

Device Name: Alara CRystalView® R200 Computed Radiography System

Indications for Use: CRystalView R200 is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061538